

NOV - 3 2003

SECTION V

510(K) Summary CryoCheck Weak Lupus Positive Control

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 5032804

Submitters Name & Address: Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia B3B 1P7
Canada

Contact Name: Stephen L. Duff – Director of New Business Development
Phone: 902-468-6422 ext. 224
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Preparation Date: September 8, 2003

Device Name & Classification: CryoCheck Weak Lupus Positive Control
Common Name: Lupus Positive Control
Classification Name: Plasma, Control, Abnormal
Regulatory Class II, 81 GGC

Predicate Device: CryoCheck Lupus Positive Control (K952623)
Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia B3B 1P7
Canada

Device Description: CryoCheck Weak Lupus Positive Control contains citrated human plasma collected from donors that have tested positive in accordance with the revised criteria of the SSC Subcommittee for the Standardization of Lupus Anticoagulants⁵. Source plasmas are processed in a manner that yields platelet-poor plasmas. Plasma is then buffered, aliquoted and rapidly frozen.

Device Intended Use: CryoCheck Weak Lupus Positive Control is prepared from human source plasma and is recommended for use as a positive control in assays for lupus anticoagulant.

⁵ Exner T, Triplett DA, Taberner D, Machin SJ. Guidelines for testing and revised criteria for lupus anticoagulant. Thromb Haemost 1991; 65:320-322.

Comparison to Predicate Device:

Parameter	CryoCheck Weak Lupus Positive Control	CryoCheck Lupus Positive Control (K952623)
Intended Use	Recommended for use as a positive control in assays for lupus anticoagulant	Recommended for use as a positive control in assays for lupus anticoagulant
Matrix	Contains citrated human plasma collected from donors that have tested positive in accordance with the revised criteria of the SSC Subcommittee for the Standardization of Lupus Anticoagulants ⁶ . Source plasmas are processed in a manner that yields platelet-poor plasmas. Plasma is then buffered, aliquoted and rapidly frozen.	Contains citrated human plasma collected from donors that have tested positive in accordance with the revised criteria of the SSC Subcommittee for the Standardization of Lupus Anticoagulants. Source plasmas are processed in a manner that yields platelet-poor plasmas. Plasma is then buffered, aliquoted and rapidly frozen
Format	Frozen	Frozen
Volume	1. 0.5 mL per vial 2. 1.0 mL per vial	1. 0.5 mL per vial 2. 1.0 mL per vial

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that CryoCheck Weak Lupus Positive Control is substantially equivalent to CryoCheck Lupus Positive Control (K952623), currently manufactured and marketed in the United States by Precision BioLogic Inc. This opinion is based on the following:

- Both products consist of human source plasma
- Both products are intended for use a positive control in assays for lupus anticoagulant.
- Both products are provided in a frozen format.

Conclusion:

CryoCheck Weak Lupus Positive Control is substantially equivalent to CryoCheck Lupus Positive Control.

⁶ Exner T, Triplett DA, Taberner D, Machin SJ. Guidelines for testing and revised criteria for lupus anticoagulant. *Thromb Haemost* 1991; 65:320-322.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Stephen L. Duff
Director of New Business Development
Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia
Canada B3B 1P7

NOV - 3 2003

Re: k032804
Trade/Device Name: CryoCheck Weak Lupus Positive Control
Regulation Number: 21 CFR § 864.5425
Regulation Name: Plasma, Control, Abnormal
Regulatory Class: II
Product Code: GGC
Dated: September 8, 2003
Received: September 12, 2003

Dear Mr. Duff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

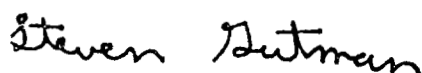
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION IV

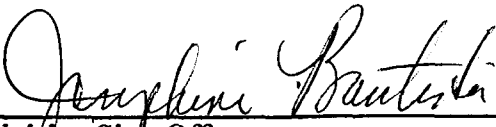
Indications for Use Statement

510(k) Number: K032804

Device Name: CryoCheck Weak Lupus Positive Control

Indications for Use:

CryoCheck Weak Lupus Positive Control is prepared from human source plasma and is recommended for use as a positive control in assays for lupus anticoagulant.


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032804